



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2012-N-0001]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 3, 2012, from 8 a.m. to 5 p.m. and on April 4, 2012, from 8 a.m. to 3:30 p.m.

Location: DoubleTree by Hilton Hotel Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is: 301 589-5200.

Contact Person: Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31-2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, e-mail: AIDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published

quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On April 3, 2012, during the morning session, the committee will discuss the development of an animal model of pneumonic plague (plague infection with extensive lung involvement) in African Green Monkeys and provide advice concerning the relevance of the animal model to pneumonic plague in humans resulting from exposure to Yersinia pestis (the bacteria that causes plague) in a bioterrorism event.

During the afternoon session, the committee will discuss the data provided to support the safety and efficacy of ciprofloxacin for the treatment of pneumonic plague in humans. The National Institute of Allergy and Infectious Diseases (NIAID) has submitted efficacy data for ciprofloxacin, based on treatment in an animal model of plague. Safety and other supportive information is derived from clinical studies and post-marketing experience in humans.

On April 4, 2012, the committee will discuss the data provided to support the safety and efficacy of levofloxacin for the treatment of pneumonic plague in humans. Johnson and Johnson Pharmaceutical Research and Development, LLC (on behalf of Janssen Pharmaceuticals, Inc.), has submitted efficacy supplements for LEVAQUIN (levofloxacin) tablets, injection, and oral solution (NDA 20-634, NDA 20-635, and NDA 21-721, respectively) for treatment of pneumonic plague. Efficacy data for levofloxacin is based on treatment in an animal model of plague. Safety and other supportive information is derived from clinical studies and post-marketing experience in humans.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior

to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at

<http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 19, 2012. Oral presentations from the public will be scheduled between approximately 10 a.m. to 10:30 a.m. and 2:30 p.m. to 3 p.m. on April 3, 2012, and between approximately 11 a.m. to 11:30 a.m. on April 4, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 16, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 19, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you

require special accommodations due to a disability, please contact Minh Doan at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for

procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 1, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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